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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,304	09/24/2003	Bronislava Gedulin	18528.643 / 0101-UTL-0	8486

7590 02/05/2008

David Marsh
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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
02/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/671,304	GEDULIN ET AL.	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

In view of the appeal brief filed on 08/24/2007, PROSECUTION IS HEREBY REOPENED. This application is made non-final for the reasons set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

(Please note that claim 17 should have been included within claims 1-16 and 18-20 of the Examiner's final office action of 01/25/2007). Therefore, claims 1-20 will be reexamined on the merit. Examiner also acknowledges that claims 21 and 22 are withdrawn from consideration.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (US 5,677,279) in further view of Brain et al. (US 7045533) and Jorgensen et al. (US 4,370,317) and for the reasons set forth in the previous Office action which are restated below.

Applicant claims a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject (i.e. human) comprising administering to said subject an effective amount of the amylin analog of 25,28,29 Pro-h-amylin, a analgesic and a pancreatic enzyme.

Young teaches a method of relieving the pain and/or treating painful inflammation disorders in a mammalian subject comprising administering to said subject an effective amount of the same amylin analog as the claimed invention amylin analog of 25,28,29 Pro-h-amylin in combination with an analgesic to treat painful inflammation disorders (see, e.g. see abstract, claims and claims 18-19 and column 4 lines 63-64). Young, however, does not teach that the mammalian subject's pain is caused by painful inflammation disorder such as pancreatitis nor Young teach the claimed pancreatic enzyme included within the composition.

Brain et al. beneficially teach that pancreatitis is a very painful inflammation condition and/or inflammation disorder (see, e.g. column 6 lines 7-14).

Jorgensen et al. beneficially teach that pancreatin treats pancreatitis (please note that pancreatin is defined as an extract from the pancreas of animals that contains pancreatic enzymes) (see, e.g. column 8 lines 36-41).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the same amylin analog as the claimed invention's amylin analog of 25,28,29 Pro-h-amylin and an analgesic to treat the painful inflammation disorder of pancreatitis in a mammalian subject because Young teaches that the amylin analog of 25,28,29 Pro-h-amylin and an analgesic treats painful inflammation disorders and Brain teaches that pancreatitis is a painful inflammation disorder. Thus, when the same amylin analog as the claimed invention's analog of 25,28,29 Pro-h-amylin in combination with an analgesic are administered to a mammalian subject for treating painful inflammation disorders, it would intrinsically treat the painful inflammation disorder of pancreatitis. Moreover, it would have been obvious to modify Young's administration's method of administering the same amylin analog as the claimed inventions amylin analog of 25,28,29 Pro-h-amylin in combination with an analgesic to include the teaching of Jorgensen which states a pancreatic enzyme such as pancreatin is well known in the art for treating pancreatitis because the above combined teachings would create an improve method of administering of treating the painful inflammation disorder of pancreatitis in a mammalian subject. The adjustments of other conventional working conditions (i.e. the substitution of the administration of one mammalian subject for another), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

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It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the same amylin analog as the claimed invention's amylin analog of 25,28,29 Pro-h-amylin and an analgesic to treat the painful inflammation disorder of pancreatitis in a mammalian subject because Young teaches that the amylin analog of 25,28,29 Pro-h-amylin and an analgesic treats painful inflammation disorders and Brain teaches that pancreatitis is a painful inflammation disorder. Thus, when the same amylin analog as the claimed invention's analog of 25,28,29 Pro-h-amylin in combination with an analgesic are administered to a mammalian subject for treating painful inflammation disorders, it would intrinsically treat the painful inflammation disorder of pancreatitis. Moreover, it would have been obvious to modify Young's administration's method of administering the same amylin analog as the claimed inventions amylin analog of 25,28,29 Pro-h-amylin in combination with an analgesic to include the teaching of Jorgensen which states a pancreatic enzyme such as pancreatin is well known in the art for treating pancreatitis because the above combined teachings would create an improve method of administering of treating the painful inflammation disorder of pancreatitis in a mammalian subject. The adjustments of other conventional working conditions (i.e. the substitution of the administration of one mammalian subject for another), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant arguments have been carefully considered but are not deemed persuasive. Applicant argues within his Appeal Brief that Young describes the use of an amylin or amylin agonist for treating agonist for treating or preventing pain. Young does not teach or suggest the use of an amylin or an amylin agonist for treating pancreatitis. Moreover, Braganza nor Jorgensen does not remedy Young's teachings because neither Braganza nor Jorgensen describes treating the pain of pancreatitis. Neither Braganza nor Jorgensen mentions or suggest the use of an amylin or an amylin agonist for use in treating pancreatitis. Therefore, alone or combined, the cited references do not teach or suggest that an amylin or an amylin analog can be used to treat pancreatitis.

Although Applicant argues the cited references of Young and Braganza and Jorgensen as a whole do not teach or suggest that an amylin or an amylin analog can be used to treat pancreatitis, Examiner in this non-final response has amended his rejection to include another cited reference (i.e. Brain et al:) to demonstrate that the above cited references of Young and Brain and Jorgensen as a whole do teach or suggest that the claimed amylin analog can be used to treat pancreatitis.

For example, Young teaches a method of relieving the pain and/or treating painful inflammation disorders in a mammalian subject comprising administering to said subject an effective amount of the same amylin analog as the claimed invention amylin analog of 25,28,29 Pro-h-amylin in combination with an analgesic to treat painful inflammation disorders (see, e.g. see abstract, claims and claims 18-19 and column 4

lines 63-64). Young, however, does not teach that the mammalian subject's pain is caused by painful inflammation disorder such as pancreatitis nor Young teach the claimed pancreatic enzyme included within the composition.

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combined teachings would create an improve method of administering of treating the painful inflammation disorder of pancreatitis in a mammalian subject. The adjustments of other conventional working conditions (i.e. the substitution of the administration of one mammalian subject for another), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTOPHER R. TATE
PRIMARY EXAMINER

TERRY MCKELVEY, PH.D.
SUPERVISORY PATENT EXAMINER